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| 10/541,078 | 02/07/2006 | Leslie Philip Miranda | 0944-UTL-GY | 4061 |
| 44638 7590 04/13/2009 Intellectual Property Department Amylin Pharmaceuticals, Inc. 9360 Towne Centre Drive San Diego, CA 92121 | | | EXAMINER HEARD, THOMAS SWEENEY | |
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| | | | 1654 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/541,078

Applicant(s)

MIRANDA ET AL.

Examiner

THOMAS S. HEARD

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-74 is/are pending in the application.
- 4a) Of the above claim(s) 73 and 74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

The Applicants Amendments to the claims received on 1/16/2009 is acknowledged. The text of those sections of Title 35 U.S. Code not included in the action can be found in the prior office action. Rejections or objections not addressed in this office action with respect to the previous office action mailed 10/16/2008 are hereby withdrawn.

Claim(s) 60 -74 are pending. Claims 62, 64, 66, and 66-74 were previously withdrawn, being drawn to non-elected subject matter. Claims 62, 64-66, and 68-72 are rejoined to the composition Claims of Claim 60. Claims 60-72 are hereby examined on the merits. Claims 73 and 74 are withdrawn, being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1661, 1666 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1666." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

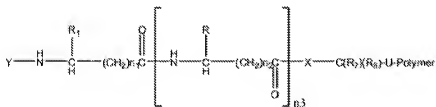
"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties,

Art Unit: 1654

(4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention.

In the instant case, the claims are drawn to compounds of the formula:



R and R₁ are individually selected from the group consisting of: hydrogen, a side chain of an amino acid, a branched alkane, a cycloalkane, an alkyl-substituted aryl or heteroaryl group, and combinations thereof;

R₇ and R₈ are each, individually, selected from hydrogen, substituted and unsubstituted linear or branched chain alkyl, aryl, heteroaryl and benzyl;

U is a linker or spacer and may be present or absent and, when present~ consists of a linear or branched chain alkyl or heteroalkyl group of up to 18 carbon atoms;

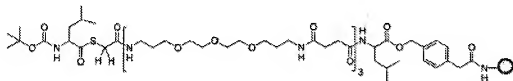
The polymer is of a formula selected from the group consisting of: -[C(O)-φ-C(O)-NH-ψ-NH]_{n₅} and -[NH-ψ-NH-C(O)-φ-C(O)]_{n₅}, where n₅ is an integer from 2 to 100, and φ and ψ are divalent radicals that may be the same or different and are selected from the group consisting of -((CH₂)_{n₆}-(CH₂CH₂O)_{n₇}-(CH₂)_{n₆})- and -((CH₂)_{n₆}-(O-CH₂-CH₂)_{n₇}-(CH₂)_{n₆})-, where n₆ is an integer from 1 to 6 and n₇ is an integer from 2-50.

(1) Level of skill and knowledge in the art:

The level of skill to practice the art of the instantly claimed invention is high with regard to synthesis, isolation, characterization, and assays to confirm that the compound is indeed what was intended in synthesis, and has the intended function that is correlated to structure.

(2) Partial structure: (3) Physical and/or chemical properties: and (4) Functional characteristics:

The partial structures made thus far are those shown in Example 3 and Example 5 where in Example 5 the Peptide-GRFN 1852- PLP3-Leu, is made from the components of:



The peptide (Y) GRFN 1852

CLSQLHSGLFLYQGLLQALEGISPELGPTLDTLQLDVFATTIW QQMEE L-thioester
(SEQ ID NO:3) (where Cys1 is Acn protected)

(5) Method of making the claimed invention:

Solid Phase and solution phase chemical synthesis.

As stated supra, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that Claim 60 is a broad generic, with respect to all possible compounds

encompassed by the claims. The possible structural variations are limitless to any class of a compound claimed in a extremely broad genus. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. There are two examples in the specification and while having written description for those two examples, one of which is shown supra, there is insufficient description of a common core structure that would allow one of skill in the art to practice the invention as claimed. The variables of R, R₁, R₇, and R₈, as well as the variance in n₁ and n₂ from 0 to 2, and n₃ from 0 to 100, does not allow for a core structure to inform one of ordinary skill in the art as what is to be made. The variance in the amino acid side chains for n₃ can be upwards of 100²⁰ (length of the amino acid chain raised to the number of amino acids used to make the peptide) is enormous and does not include the variance in n₂ or the inclusion of other side chains that do not correspond to the side chains of amino acids. Further, the polymer for the instant invention is also variant in structure as well, that of C(R₇)(R₈)-U-Polymer, as is the linker and U, that there is no real common core structure for the linker-polymer.

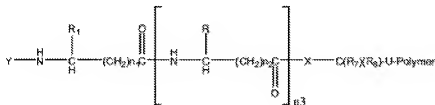
The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re

Wilder, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Applicant's Arguments

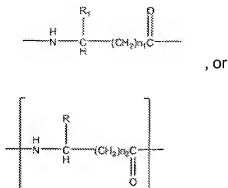
Applicants have argued that the polymer portion of the formula



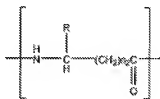
does provide support for the compounds shown in the specification, showing how each of the variable are related to a specific structure in the specification, see pages 9, 10, and the four lines of page 11. It is also stated that the structure is described solely on its structure and not its function, reciting a portion of the written description in the previous office action. It is finally argued that examples of actual reduction to practice are found within the specification, and what is conventional in the art need not be disclosed in detail, see page 8 of applicants response.

Response to Applicants Arguments

Applicants arguments have been carefully considered but are not deemed persuasive to overcome the rejection. Applicants have overcome a part of the rejection, arguing that the polymer is of a formula selected from the group consisting of: $-\text{C}(\text{O})-\phi-\text{C}(\text{O})-\text{NH}-\psi-\text{NH}]n_5$ and $-\text{[NH}-\psi-\text{NH}-\text{C}(\text{O})-\phi-\text{C}(\text{O})]n_5$, where n_5 is an integer from 2 to 100, and ϕ and ψ are divalent radicals that may be the same or different and are selected from the group consisting of $-(\text{CH}_2)_{n_6}-(\text{CH}_2\text{CH}_2\text{O})_{n_7}-(\text{CH}_2)_{n_6}-$ and $-(\text{CH}_2)_{n_6}-(\text{O}-\text{CH}_2-\text{CH}_2)_{n_7}-(\text{CH}_2)_{n_6}-$, where n_6 is an integer from 1 to 6 and n_7 is an integer from 2-50, and this description does appear to read on the species within the specification. However, this is not the complete reason for the written description. It is the enormous variance in the entire molecule for R , R_1 , R_7 , and R_8 , as well as the variance in n_1 and n_2 from 0 to 2, and n_3 from 0 to 100, that does not allow for a core structure to inform one of ordinary skill in the art as what is to be made. Y could be an di-peptide attached to X , attached to $-(\text{CH})_2-$ (R_7 and R_8 being H), which is attached to a large genus of polymers of different lengths. Y could also be untold number of different polypeptides that are attached to untold combinations of subunits where n_2 is 0 or 2, and n_3 is any range from 1 to 100, which is then attached to an extremely large polymer genus. What is disclosed in the specification is of very limited range and scope compared to what is claimed, and there is not a sufficient number of representative samples to show that the Applicants were in possession, at the time of filing, of the entire genus. The peptide species in the specification could be Y , or could be



The overall "core" that Applicant's argue in the response on page 9 is the breaking apart of a number of genus' such as those represented above into smaller genus'. As such, it



is not described when Y is any different from n_2 when n_2 is zero.

It is because of the extremely large genus encompassed by the Formula of Claim 1, and only two examples to support such a large genus, that the invention as claimed lacks written description. The rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Prior art contained in the reference of record can be applied in the next office action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas S. Heard** whose telephone number is **(571) 272-2064**. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas S Heard/
Examiner, Art Unit 1654

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

